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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,401	04/26/2000	Hiroiyuki Yuyama	2000 0523A	1206

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EXAMINER

GILLIGAN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/559,401	Applicant(s) YUYAMA ET AL.	
	Examiner Luke Gilligan	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2005.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-37 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 19-37 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/21/05 has been entered.

Response to Amendment

2. In the amendment filed 2/22/05, the following has occurred: claims 10-18 have been canceled and claims 19-37 have been added. Now, claims 19-37 are presented for examination.

Claim Objections

3. Claim 37 is objected to because of the following informalities: It appears that claim 37 should depend from claim 36 rather than claim 35 since "the composition alteration caused due to the combination" is recited in claim 36 and not claim 35. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 19-20, 24-29, 31-32, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Bloom et al., U.S. Patent No. 6,070,761.

6. As per claim 19, Bloom teaches an apparatus for supporting injection mixing work, said apparatus comprising: an acquisition unit operable to acquire an injection prescription data including data specifying a plurality of injections which are prescribed to a patient (see column 8, lines 13-21); a decision unit operable to decide a proper mixing order of the plurality of injections included in the injection prescription data acquired by said acquisition unit (see column 33, lines 35-41, the Examiner is interpreting the application of the IV Template parameters for dose administration to be a form of a decision unit operable to decide a proper mixing order; also note that the medication management system can detect scheduling conflicts as shown in the table at column 34); and a display unit operable to display an indication representing the mixing order decided by said decision unit (see column 33, lines 45-55).

7. As per claim 20, Bloom teaches the apparatus of claim 19 as described above. Bloom further teaches a memory unit operable to store corresponding relations between data specifying injections and data for deciding a mixing order of the injections (see column 11, lines 34-40); wherein said decision unit is operable to decide the proper mixing order of the plurality of injections based on the data for deciding the mixing order corresponding to the data specifying injections which are included in the injection prescription data acquired by said acquiring unit (see column 33, lines 35-41).

8. As per claim 24, Bloom teaches the apparatus of claim 20 as described above. Bloom further teaches said memory unit is further operable to store corresponding relations between data specifying injections and data identifying whether or not the injections need sole administration (see column 37, lines 4-11); and said decision unit is operable to decide the

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proper mixing order of the plurality of injections based on the data for deciding the mixing order and the data identifying whether or not the injections need sole administration (see column 33, lines 35-41).

9. As per claim 25, Bloom teaches the apparatus of claim 20 as described above. Bloom further teaches said memory unit is further operable to store corresponding relations between a combination of injections and data showing a degree to which the combination of injections is improper (see column 11, lines 15-28); said apparatus further includes a judging unit operable to judge whether or not any improper combination is present for the injections included in the injection prescription data acquired based on the corresponding relations between combination of injections and data showing the degree to which the combination of injections is improper (see column 11, lines 28-32); and for the injections which are judged to be an improper combination by said judging unit, said display unit is operable to display an indication showing the degree to which the combination of injections is improper (see column 11, lines 28-32).

10. As per claim 26, Bloom teaches the apparatus of claim 25 as described above. Bloom further teaches an operation unit operable to record the corresponding relations between combination of injections and data showing a degree to which the combination of injections is improper onto said memory unit (see column 12, lines 26-28).

11. As per claim 27, Bloom teaches the apparatus of claim 20 as described above. Bloom further teaches said memory unit is further operable to store corresponding relations between data specifying injections and matters requiring attention when using the injections (see column 11, lines 34-40); and said display unit is operable to display the matters requiring attention when using the injections corresponding to the data specifying the injections (see column 11, lines 56-64).

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12. As per claim 28, Bloom teaches the apparatus of claim 19 as described above. Bloom further teaches the indication representing the mixing order decided by said decision unit includes names of the plurality of injections included in the injection prescription data acquired by said acquiring unit (see column 37, lines 4-16).

13. As per claim 29, Bloom teaches the apparatus of claim 28 as described above. Bloom further teaches said display unit is operable to display an indication for identifying the name of an injection as to the injection to be mixed subsequently (see column 37, lines 4-16).

14. As per claim 31, Bloom teaches the apparatus of claim 19 as described above. Bloom further teaches the indication representing the mixing order decided by said decision unit includes an indication representing that the injections included in the injection prescription data acquired by said acquiring unit needs sole administration (see column 37, lines 34-45).

15. As per claim 32, Bloom teaches the apparatus of claim 19 as described above. Bloom further teaches the indication representing the mixing order decided by said decision unit includes an indication representing that the injections included in the injection prescription data acquired by said acquiring unit are not a proper combination (see column 37, lines 34-45).

16. As per claim 34, Bloom teaches the apparatus of claim 19 as described above. Bloom further teaches an input unit operable to input data specifying injections to be mixed subsequently (see column 36, lines 52-61); and a comparison unit operable to compare the data specifying injections inputted with the data specifying injections to be mixed subsequently (see column 36, line 64 – column 37, line 3); wherein said display unit is operable to display an indication that the comparison by said comparison unit results in an inconsistency (see column 37, lines 4-16).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 21-23 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom et al., U.S. Patent No. 6,070,761 in view of Yuyama et al., U.S. Patent No. 6,308,109.

19. As per claim 21, Bloom teaches the apparatus of claim 20 as described above. Bloom further teaches said memory unit is further operable to store corresponding relations between data specifying injections and data identifying the type of injections (see column 11, lines 34-40); and said decision unit is operable to decide the proper mixing order of the plurality of injections based on the data for deciding the mixing order and the data identifying the type of injections (see column 33, lines 35-41). Bloom does not explicitly teach that the type of injections are transfusions. However, providing medication as a transfusion is old and well known in the art as evidenced by Yuyama (see column 4, lines 57-59). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate data identifying transfusions into the pharmaceutical database, drug parameters, and IV template information of Bloom. One of ordinary skill in the art would have been motivated to incorporate this data for the purpose of facilitation the drug delivery goals of Bloom by enabling verification of types of drug delivery forms that are old and well known in the art (see column 5, lines 40-49 of Bloom).

20. As per claim 22, Bloom in view of Yuyama teach the apparatus of claim 21 as described above. Bloom further teaches said memory unit is further operable to store corresponding relations between data specifying injections and data identifying whether or not the injections

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need sole administration (see column 37, lines 4-11); and said decision unit is operable to decide the proper mixing order of the plurality of injections based on the data for deciding the mixing order, the data identifying the type of injections, and the data identifying whether or not the injections need sole administration (see column 33, lines 35-41). Although Bloom does not explicitly teach that the type of injections are transfusions, this type of medication administration is old and well known in the art as described above with respect claim 21.

21. As per claim 23, Bloom in view of Yuyama teach the apparatus of claim 22 as described above. Bloom further teaches that the display unit is operable to display an indication representing the type of injection (see column 20, lines 24-35); and for the injections in need or sole administration, said display unit is operable to display an indication representing that the injection needs sole administration (see column 11, lines 28-45). Although Bloom does not explicitly teach that the type of injections are transfusions, this type of medication administration is old and well known in the art as described above with respect claim 21.

22. As per claim 30, Bloom teaches the apparatus of claim 19 as described above. Bloom further teaches the indication representing the mixing order decided by said decision unit includes an indication representing that the injections included in the injection prescription data acquired by said acquiring unit is a type of injection (see column 37, lines 34-45). Bloom does not explicitly teach that the type of injections are transfusions. However, providing medication as a transfusion is old and well known in the art as evidenced by Yuyama (see column 4, lines 57-59). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate data identifying transfusions into the pharmaceutical database, drug parameters, and IV template information of Bloom. One of ordinary skill in the art would have been motivated to incorporate this data for the purpose of facilitation the drug delivery goals of Bloom

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by enabling verification of types of drug delivery forms that are old and well known in the art (see column 5, lines 40-49 of Bloom).

23. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom et al., U.S. Patent No. 6,070,761 in view of Merki et al., U.S. Patent No. 5,002,055.

24. As per claim 33, Bloom teaches the apparatus of claim 19 as described above. Bloom does not explicitly teach the data for deciding the mixing order is pH-values data. Merki teaches storing pH-values data for injections, and wherein a controller decides a mixing order of the injections in accordance with the pH-values (see column 3, lines 52-63). It would have been obvious to one of ordinary skill in the art of injection prescription management at the time of the invention to incorporate this feature into the system of Bloom. One of ordinary skill in the art would have been motivated to incorporate this data for the purpose of facilitation the drug delivery goals of Bloom by enabling verification of types of drug delivery forms that are old and well known in the art (see column 5, lines 40-49 of Bloom).

25. Claim 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom et al., U.S. Patent No. 6,070,761 in view of Leissing et al., U.S. Patent No. 5,281,396.

26. As per claim 35, Bloom teaches the apparatus of claim 19 as described above. Bloom does not explicitly teaches recording a composition alteration. Leissing teaches an operation unit operable to operate to record a composition alteration (see column 6, lines 10-23); and a recorder operable to record the composition alteration (see column 6, liens 60-68). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Bloom. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of providing trustworthy information to aid the

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physician in administering injections to patients in the system of Bloom (see column 3, lines 33-35 of Leissing).

27. As per claim 36, Bloom in view of Leissing teach the apparatus of claim 35 as described above. Bloom does not explicitly teach that the composition alteration is caused due to the combination of the plurality of injections. Leissing further teaches that the composition alteration is caused due to the combination of a plurality of intravenous drugs (see column 6, lines 24-29). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Bloom for the reasons given above with respect to claim 35.

28. As per claim 37, Bloom in view of Leissing teach the apparatus of claim 35 as described above. Bloom further teaches a mixing result flag (see column 11, lines 27-32). Bloom does not explicitly teach that the composition alteration is caused due to the combination of the plurality of injections. Leissing further teaches that the composition alteration is caused due to the combination of a plurality of intravenous drugs (see column 6, lines 24-29). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Bloom for the reasons given above with respect to claim 35.

Response to Arguments

29. In the remarks filed 2/22/05, Applicants argue in substance that none of the applied prior art teach determining a proper mixing order.

30. In response to Applicants' argument, the Examiner respectfully submits that the rejections in view of Engleson have been withdraw. Therefore, the arguments with respect to the Engleson reference are now moot in view of the new grounds of rejection detailed above. Furthermore, the Examiner respectfully refers to the new grounds of rejection in view of Bloom

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detailed above and, in particular, to paragraph 6 for reference to determining a proper mixing order.

Conclusion

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (571) 272-6770. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

32. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

33. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


7/8/05


C. Luke Gilligan
Patent Examiner
Art Unit 3626